refer to the location of, the following information: The dates of manufacture, the quantity manufactured, the quantity released for distribution, and any control number used.

§ 820.185 Critical devices, device history record.

In addition to the requirements of § 820.184, the following requirements apply to critical devices: There shall be a critical device history record for each control number, which shall include complete information relating to the production unit. This record shall identify the specific label, labeling, and control number used for each production unit and shall be readily accessible and maintained by a designated individual(s). The device history record shall include, or refer to the location of, the following:

(a) *Component documentation.* The documentation of each critical component used in the manufacture of a device shall include:

(1) *Control number.* The control number designating each critical component or lot of critical components used in the manufacture of a device.

(2) *Acceptance record.* The acceptance record of the critical component, including acceptance date and signature of the recipient.

(b) *Record of critical operation.* The record of, or reference to, each critical operation, identifying the date performed, the designated individual(s) performing the operation and, when appropriate, the major equipment used.

(c) *Inspection checks.* The inspection checks performed, the methods and equipment used, results, the date, and signature of the inspecting individual.

§ 820.195 Critical devices, automated data processing.

When automated data processing is used for manufacturing or quality assurance purposes, adequate checks shall be designed and implemented to prevent inaccurate data output, input, and programming errors.

§ 820.198 Complaint files.

(a) Written and oral complaints relative to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device shall be reviewed, evaluated, and maintained by a formally designated unit. This unit shall determine whether or not an investigation is necessary. When no investigation is made, the unit shall maintain a record that includes the reason and the name of the individual responsible for the decision not to investigate.

(b) Any complaint involving the possible failure of a device to meet any of its performance specifications shall be reviewed, evaluated, and investigated. Any complaint pertaining to injury, death, or any hazard to safety shall be immediately reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint file.

(c) When an investigation is made, a written record of each investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include the name of the device, any control number used, name of complainant, nature of complaint, and reply to complainant.

(d) Where the formally designated unit is located at a site separate from the actual manufacturing establishment, a duplicate copy of the record of investigation of any complaint shall be transmitted to and maintained at the actual manufacturing establishment in a file designated for device complaints.

PART 821—MEDICAL DEVICE TRACKING REQUIREMENTS

Subpart A—General Provisions

Sec.

Subpart B—Tracking Requirements

Subpart C—Additional Requirements and Responsibilities

Subpart D—Records and Inspections

AUTHORITY: Secs. 301, 501, 502, 510, 515, 518, 519, 701, and 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 351, 352, 360, 360e, 360h, 360i, 371, and 374).

SOURCE: 58 FR 43447, Aug. 16, 1993, unless otherwise noted.

Subpart A—General Provisions

§ 821.1 Scope.

(a) The regulations in this part implement section 519(e) of the Federal Food, Drug, and Cosmetic Act (the act) which requires the adoption of a method of device tracking by any person who registers under section 510 of the act and is engaged in the manufacture and distribution of devices the failure of which would be reasonably likely to have serious adverse health consequences if the devices are life-sustaining or life-supporting devices used outside of a device user facility or are permanently implantable devices. This part also applies to any other device that the Food and Drug Administration (FDA) designates as requiring a method of tracking to protect the public health. A device subject to this part either by statutory requirement or by FDA designation is referred to herein as a ''tracked device.''

(b) These regulations are intended to ensure that tracked devices can be traced from the device manufacturing facility to the person for whom the device is indicated, that is, the patient. Effective tracking of devices from the manufacturing facility, through the distributor network (including distributors, retailers, rental firms and other commercial enterprises, device user facilities and licensed practitioners) and, ultimately, to any person for whom the device is intended is necessary for the effectiveness of remedies prescribed by the act, such as patient notification (section 518(a) of the act) or device recall (section 518(e) of the act). Although these regulations do not preclude a manufacturer from involving outside organizations in that manufacturer's device tracking effort, the legal responsibility for complying with this part rests with manufacturers who must register under section 510 of the act, and that responsibility cannot be altered, modified, or in any way abrogated by contracts or other agreements.

(c) Each manufacturer of a tracked device shall implement a method of tracking devices by August 29, 1993.

(d) The primary burden for ensuring that the tracking system works rests upon the manufacturer. A manufacturer or any other person, including a distributor, final distributor, or multiple distributor, who distributes a device subject to tracking, who fails to comply with any applicable requirement of section 519(e) of the act or of this part, or any person who causes such failure, misbrands the device within the meaning of section 501(t)(2) of the act and commits a prohibited act within the meaning of sections 301(e) and 301(q)(1)(B) of the act.

(e) Any person subject to this part who permanently discontinues doing business is required to notify FDA at the time the person notifies any government agency, court, or supplier, and provide FDA with a complete set of its tracking records and information. However, if a person ceases distribution of a tracked device but continues to do other business, that person continues to be responsible for compliance with this part unless another person, affirmatively and in writing, assumes responsibility for continuing the tracking of devices previously distributed under this part. Further, if a person subject to this part goes out of business completely, but other persons acquire the right to manufacture or distribute tracked devices, those other persons are deemed to be responsible for continuing the tracking responsibility of the previous person under this part.

§ 821.2 Exemptions and variances.

(a) A manufacturer, importer, or distributor may seek an exemption or variance from one or more requirements of this part.

(b) A request for an exemption or variance shall be submitted in the form of a petition under § 10.30 of this chapter and shall comply with the requirements set out therein, except that a re-

sponse shall be issued in 90 days. The Director or Deputy Directors, CDRH, or the Director, Office of Compliance, CDRH, shall issue responses to requests under this section. The petition shall also contain the following:

(1) The name of the device and device class and representative labeling showing the intended use(s) of the device;

(2) The reasons that compliance with the tracking requirements of this part is unnecessary;

(3) A complete description of alternative steps that are available, or that the petitioner has already taken, to ensure that an effective tracking system is in place; and

(4) Other information justifying the exemption or variance.

(c) An exemption or variance is not effective until the Director, Office of Compliance and Surveillance, CDRH, approves the request under §10.30(e)(2)(i) of this chapter.

(d) For petitions received under this section before August 29, 1993, FDA will, within 60 days, approve or disapprove the petition or extend the effective date of this part for the device that is the subject of the petition. Any extension that FDA grants to the effective date will be based upon the additional time FDA needs to complete its review of the petition.

[58 FR 43447, Aug. 16, 1993, as amended at 59 FR 31138, June 17, 1994]

§821.3 Definitions.

The following definitions and terms apply to this part:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 321 et seq., as amended.

(b) *Importer* means the initial distributor of an imported device who is required to register under section 510 of the act and §807.20 of this chapter. ''Importer'' does not include anyone who only performs a service for the person who furthers the marketing, i.e., brokers, jobbers, or warehousers.

(c) *Manufacturer* means any person, including any importer, repacker and/or relabeler, who manufactures, prepares, propagates, compounds, assembles, or processes a device or engages in any of the activities described in §807.3(d) of this chapter.

(d) *Device failure* means the failure of a device to perform or function as intended, including any deviations from the device's performance specifications or intended use.

(e) *Serious adverse health consequences* means any significant adverse experience related to a device, including device-related events which are life-threatening or which involve permanent or long-term injuries or illnesses.

(f) *Permanently implantable device* means a device that is intended to be placed into a surgically or naturally formed cavity of the human body to continuously assist, restore, or replace the function of an organ system or structure of the human body throughout the useful life of the device. The term does not include any device which is intended and used for temporary purposes or which is intended for explantation.

(g) *Life-supporting or life-sustaining device used outside a device user facility* means a device which is essential, or yields information that is essential, to the restoration or continuation of a bodily function important to the continuation of human life that is intended for use outside a hospital, nursing home, ambulatory surgical facility, or diagnostic or outpatient treatment facility. Physicians' offices are not device user facilities and, therefore, devices used therein are subject to tracking if they otherwise satisfy the statutory and regulatory criteria.

(h) *Distributor* means any person who furthers the distribution of a device from the original place of manufacture to the person who makes delivery or sale to the ultimate user, i.e., the final or multiple distributor, but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package.

(i) *Final distributor* means any person who distributes a tracked device intended for use by a single patient over the useful life of the device to the patient. This term includes, but is not limited to, licensed practitioners, retail pharmacies, hospitals, and other types of device user facilities.

(j) *Distributes* means any distribution of a tracked device, including the charitable distribution of a tracked device. This term does not include the dis-

tribution of a device under an effective investigational device exemption in accordance with section 520(g) of the act and part 812 of this chapter or the distribution of a device for teaching, law enforcement, research, or analysis as specified in § 801.125 of this chapter.

(k) *Multiple distributor* means any device user facility, rental company, or any other entity that distributes a life-sustaining or life-supporting device intended for use by more than one patient over the useful life of the device.

(l) *Licensed practitioner* means a physician, dentist, or other health care practitioner licensed by the law of the State in which he or she practices to use or order the use of the tracked device.

(m) Any term defined in section 201 of the act shall have the same definition in this part.

§ 821.4 Imported devices.

For purposes of this part, the importer of a tracked device shall be considered the manufacturer and shall be required to comply with all requirements of this part applicable to manufacturers. Importers must keep all information required under this part in the United States.

Subpart B—Tracking Requirements

§ 821.20 Devices subject to tracking.

(a) A manufacturer of any device the failure of which would be reasonably likely to have a serious adverse health consequence, that is either a life-sustaining or life-supporting device used outside of a device user facility or a permanently implantable device, or a manufacturer of any other device that FDA, in its discretion, designates for tracking, shall track that device in accordance with this part.

(b) Manufacturers have the responsibility to identify devices that meet the criteria for tracking and to initiate tracking. By way of illustration and to provide guidance, FDA has set out below a list of example devices it regards as subject to tracking under the criteria set forth in this regulation.

(1) Permanently implantable devices.

21 CFR	Classification
870.3450	Vascular graft prosthesis of less than 6 millimeters diameter
870.3460	Vascular graft prosthesis of 6 millimeters and greater diameter
(no cite)	Total temporomandibular joint prosthesis.
(no cite)	Glenoid fossa prosthesis.
(no cite)	Mandibular condyle prosthesis.
(no cite)	Interarticular disc prosthesis (interpositional implant).
870.3545	Ventricular bypass (assist) device
870.3610	Implantable pacemaker pulse generator
870.3680	Cardiovascular permanent pacemaker electrode
870.3800	Annuloplasty ring
870.3925	Replacement heart valve
(no cite)	Automatic implantable cardioverter/defibrillator
878.3720	Tracheal prosthesis
882.5820	Implanted cerebellar stimulator
882.5830	Implanted diaphragmatic/phrenic nerve stimulator
(no cite)	Implantable infusion pumps

(2) Life-sustaining or life-supporting devices used outside device user facilities

21 CFR	Classification
868.2375	Breathing frequency monitors (apnea monitors) (including ventilatory efforts monitors)
868.5895	Continuous ventilator
870.5300	DC-defibrillator and paddles

(c) FDA designates the following devices as subject to tracking. Manufacturers must track these devices in accordance with this part.

21 CFR	Classification
876.3350	Penile inflatable implant
878.3530	Silicone inflatable breast prosthesis
878.3540	Silicone gel-filled breast prosthesis
876.3750	Testicular prosthesis, silicone gel-filled
(no cite)	Silicone gel-filled chin prosthesis
(no cite)	Silicone gel-filled angel chik reflux valve
880.5725	Infusion pumps

(d) FDA, when responding to premarket notification submissions and approving premarket approval applications, will notify the sponsor that FDA believes the device meets the criteria of section 519(e)(1) and therefore should be tracked. FDA will also, after notifying the sponsor, publish a notice in the FEDERAL REGISTER announcing that FDA believes a new generic type of device is subject to tracking and soliciting comment on FDA's position. If the device is a new generic type of device

not already on the example list above, FDA will add it to this list.

[58 FR 43447, Aug. 16, 1993, as amended at 58 FR 43455, Aug. 16, 1993; 59 FR 15052, Mar. 31, 1994.]

§821.25 Device tracking system and content requirements: manufacturer requirements.

(a) A manufacturer of a tracked device shall adopt a method of tracking for each such type of device that it distributes that enables a manufacturer to provide FDA with the following information in writing for each tracked device distributed:

(1) Except as required by order under section 518(e) of the act, within 3 working days of a request from FDA, prior to the distribution of a tracked device to a patient, the name, address, and telephone number of the distributor, multiple distributor, or final distributor holding the device for distribution and the location of the device;

(2) Within 10 working days of a request from FDA for life-sustaining or life-supporting devices used outside a device user facility that are intended for use by a single patient over the life of the device and permanent implants that are tracked devices, after distribution to or implantation in a patient:

(i) The lot number, batch number, model number, or serial number of the device or other identifier necessary to provide for effective tracking of the devices;

(ii) The date the device was shipped by the manufacturer;

(iii) The name, address, telephone number, and social security number (if available) of the patient receiving the device;

(iv) The date the device was provided to the patient;

(v) The name, mailing address, and telephone number of the prescribing physician;

(vi) The name, mailing address, and telephone number of the physician regularly following the patient if different than the prescribing physician; and

(vii) If applicable, the date the device was explanted and the name, mailing address, and telephone number of the explanting physician; the date of the patient's death; or the date the device was returned to the manufacturer, permanently retired from use, or otherwise permanently disposed of.

(3) Except as required by order under section 518(e) within 10 working days of a request from FDA for life-sustaining or life-supporting devices used outside device user facilities that are intended for use by more than one patient and that are tracked devices, after the distribution of the device to the multiple distributor:

(i) The lot model number, batch number, serial number of the device or other identifier necessary to provide for effective tracking of the device;

(ii) The date the device was shipped by the manufacturer;

(iii) The name, address, and telephone number of the multiple distributor;

(iv) The name, address, telephone number, and social security number (if available) of the patient using the device;

(v) The location of the device;

(vi) The date the device was provided for use by the patient;

(vii) The name, address, and telephone number of the prescribing physician; and

(viii) If and when applicable, the date the device was returned to the manufacturer, permanently retired from use, or otherwise permanently disposed of.

(b) A manufacturer of a tracked device shall keep current records in accordance with its standard operating procedure of the information identified in paragraphs (a)(1), (a)(2) and (a)(3)(i) through (a)(3)(iii) of this section on each tracked device released for distribution for as long as such device is in use or in distribution for use.

(c) A manufacturer of a tracked device shall establish a written standard operating procedure for the collection, maintenance, and auditing of the data specified in paragraphs (a) and (b) of this section. A manufacturer shall make this standard operating procedure available to FDA upon request. A manufacturer shall incorporate the following into the standard operating procedure:

(1) Data collection and recording procedures, which shall include a procedure for recording when data which is required under this part is missing and could not be collected and the reason

why such required data is missing and could not be collected;

(2) A method for recording all modifications or changes to the tracking system or to the data collected and maintained under the tracking system, reasons for any modification or change, and dates of any modification or change. Modification and changes included under this requirement include modifications to the data (including termination of tracking), the data format, the recording system, and the file maintenance procedures system; and

(3) A quality assurance program that includes an audit procedure to be run for each device product subject to tracking, at not less than 6-month intervals for the first 3 years of distribution and at least once a year thereafter. This audit procedure shall provide for statistically relevant sampling of the data collected to ensure the accuracy of data and performance testing of the functioning of the tracking system.

(d) When a manufacturer becomes aware that a distributor, final distributor, or multiple distributor has not collected, maintained, or furnished any record or information required by this part, the manufacturer shall notify the FDA district office responsible for the area in which the distributor, final distributor, or multiple distributor is located of the failure of such persons to comply with the requirements of this part. Manufacturers shall have taken reasonable steps to obtain compliance by the distributor, multiple distributor, or final distributor in question before notifying FDA.

(e) A manufacturer may petition for an exemption or variance from one or more requirements of this part according to the procedures in §821.2 of this chapter.

Subpart C—Additional Requirements and Responsibilities

§ 821.30 Tracking obligations of persons other than device manufacturers: distributor requirements.

(a) A distributor, final distributor, or multiple distributor of any tracked device shall, upon purchasing or otherwise acquiring any interest in such a device, promptly provide the manufacturer tracking the device with the following information:

(1) The name and address of the distributor, final distributor or multiple distributor;

(2) The lot number, batch number, model number, or serial number of the device or other identifier used by the manufacturer to track the device;

(3) The date the device was received;

(4) The person from whom the device was received;

(5) If and when applicable, the date the device was explanted, the date of the patient's death, or the date the device was returned to the distributor, permanently retired from use, or otherwise permanently disposed of.

(b) A final distributor, upon sale or other distribution of a tracked device for use in or by the patient, shall promptly provide the manufacturer tracking the device with the following information:

(1) The name and address of the final distributor,

(2) The lot number, batch number, model number, or serial number of the device or other identifier used by the manufacturer to track the device;

(3) The name, address, telephone number, and social security number (if available) of the patient receiving the device;

(4) The date the device was provided to the patient or for use in the patient;

(5) The name, mailing address, and telephone number of the prescribing physician;

(6) The name, mailing address, and telephone number of the physician regularly following the patient if different than the prescribing physician; and

(7) When applicable, the date the device was explanted and the name, mailing address, and telephone number of the explanting physician, the date of the patient's death, or the date the device was returned to the manufacturer, permanently retired from use, or otherwise permanently disposed of.

(c)(1) A multiple distributor shall keep written records of the following each time such device is distributed for use by a patient:

(i) The lot number, batch number, or model number, or serial number of the device or other identifier used by the manufacturer to track the device;

(ii) The name, address, telephone number, and social security number (if available) of the patient using the device;

(iii) The location of the device;

(iv) The date the device was provided for use by the patient;

(v) The name, address, and telephone number of the prescribing physician;

(vi) The name, address, and telephone number of the physician regularly following the patient if different than the prescribing physician; and

(vii) When applicable, the date the device was permanently retired from use or otherwise permanently disposed of.

(2) Except as required by order under section 518(e) of the act, any person who is a multiple distributor subject to the recordkeeping requirement of paragraph (c)(1) of this section shall, within 5 working days of a request from the manufacturer or within 10 working days of a request from FDA for the information identified in paragraph (c)(1) of this section, provide such information to the manufacturer or FDA.

(d) A distributor, final distributor, or multiple distributor shall make any records required to be kept under this part available to the manufacturer of the tracked device for audit upon written request by an authorized representative of the manufacturer.

(e) A distributor, final distributor, or multiple distributor may petition for an exemption or variance from one or more requirements of this part according to the procedures in §821.2.

Subpart D—Records and Inspections

§821.50 Availability.

(a) Manufacturers, distributors, multiple distributors, and final distributors shall, upon the presentation by an FDA representative of official credentials and the issuance of Form FD 482 at the initiation of an inspection of an establishment or person under section 704 of the act, make each record and all information required to be collected and maintained under this part and all records and information related to the events and persons identified in such records available to FDA personnel.

(b) Records and information referenced in paragraph (a) of this section shall be available to FDA personnel for purposes of reviewing, copying, or any other use related to the enforcement of the act and this part. Records required to be kept by this part shall be kept in a centralized point for each manufacturer or distributor within the United States.

§821.55 Confidentiality.

(a) Records and other information submitted to FDA under this part shall be protected from public disclosure to the extent permitted under part 20 of this chapter, and in accordance with §20.63 of this chapter, information contained in such records that would identify patient or research subjects shall not be available for public disclosure except as provided in those parts.

(b) Patient names or other identifiers may be disclosed to a manufacturer or other person subject to this part or to a physician when the health or safety of the patient requires that such persons have access to the information. Such notification will be pursuant to agreement that the record or information will not be further disclosed except as the health aspects of the patient requires. Such notification does not constitute public disclosure and will not trigger the availability of the same information to the public generally.

§821.60 Retention of records.

Persons required to maintain records under this part shall maintain such records for the useful life of each tracked device they manufacture or distribute. The useful life of a device is the time a device is in use or in distribution for use. For example, a record may be retired if the person maintaining the record becomes aware of the fact that the device is no longer in use, has been explanted, returned to the manufacturer, or the patient has died.

PART 860—MEDICAL DEVICE CLASSIFICATION PROCEDURES

Subpart A—General

Subpart B—Classification

Subpart C—Reclassification

AUTHORITY: Secs. 513, 514, 515, 519, 520, 701, 704 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c, 360d, 360e, 360i, 360j, 371, 374).

SOURCE: 43 FR 32993, July 28, 1978, unless otherwise noted.

Subpart A—General

§ 860.1 Scope.

(a) This part implements sections 513, 514(b), 515(b), and 520(l) of the act with respect to the classification and reclassification of devices intended for human use.

(b) This part prescribes the criteria and procedures to be used by classification panels in making their recommendations and by the Commissioner in making the Commissioner's determinations regarding the class of regulatory control (class I, class II, or class III) appropriate for particular devices. Supplementing the general Food and Drug Administration procedures governing advisory committees (Part 14 of this chapter), this part also provides procedures for manufacturers, importers, and other interested persons to participate in proceedings to classify and reclassify devices. This part also describes the kind of data required for determination of the safety and effectiveness of a device, and the circumstances under which information submitted to classification panels or to the Commissioner in connection with classification and reclassification proceedings will be available to the public.

§ 860.3 Definitions.

For the purposes of this part:

(a) *Act* means the Federal Food, Drug, and Cosmetic Act.

(b) *Commissioner* means the Commissioner of Food and Drugs, Food and Drug Administration, United States Department of Health and Human Services, or the Commissioner's designee.

(c) *Class* means one of the three categories of regulatory control for medical devices, defined below:

(1) *Class I* means the class of devices that are subject to only the general controls authorized by or under sections 501 (adulteration), 502 (misbranding), 510 (registration), 516 (banned devices), 518 (notification and other remedies), 519 (records and reports), and 520 (general provisions) of the act. A device is in class I if (i) general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, or (ii) there is insufficient information from which to determine that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but the device is not life-supporting or life-sustaining or for a use which is of substanial importance in preventing impairment of human health, and which does not present a potential unreasonable risk of illness of injury.

(2) *Class II* means the class of devices that is or eventually will be subject to special controls. A device is in class II if general controls alone are insufficient to provide reasonable assurance